



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-D-0849]

Draft Guidance for Industry on Suicidal Ideation and Behavior: Prospective Assessment of Occurrence in Clinical Trials; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled “Suicidal Ideation and Behavior: Prospective Assessment of Occurrence in Clinical Trials.” The purpose of this guidance is to assist sponsors in prospectively assessing the occurrence of treatment-emergent suicidal ideation and behavior in clinical trials of drug and biological products, including drugs for psychiatric and nonpsychiatric indications. This guidance revises and replaces a previous draft guidance entitled “Suicidality: Prospective Assessment of Occurrence in Clinical Trials” issued in September 2010.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993-0002. Send one

self-addressed adhesive label to assist that office in processing your requests. See the SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to <http://www.regulations.gov>.

Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled “Suicidal Ideation and Behavior: Prospective Assessment of Occurrence in Clinical Trials.” The purpose of this guidance is to assist sponsors in prospectively assessing the occurrence of treatment-emergent suicidal ideation and behavior in clinical trials of drug and biological products. Specifically, this guidance addresses FDA’s current thinking regarding the importance of suicidal ideation and behavior assessment in psychiatric and nonpsychiatric drug trials and the general principles for how best to accomplish this assessment during drug development.

Prospective assessment of suicidal ideation and behavior involves actively querying patients about the occurrence of suicidal thinking and behavior, rather than relying on patients to report such occurrences spontaneously, followed by retrospective classification of events into appropriate categories. This guidance recommends a specific suicidal ideation and behavior assessment instrument that can be used to conduct such prospective assessments and offers guidance on the use of alternative instruments.

This guidance is intended to serve as a focus for continued discussions among FDA, pharmaceutical sponsors, the academic community, and the public. This guidance does not address the complex analytic issues involved in the analysis of the suicidal ideation and behavior data that will be derived from prospective assessments of suicidal ideation and behavior; these issues will be addressed in separate guidances.

This guidance is a revision of the draft guidance for industry entitled “Suicidality: Prospective Assessment of Occurrence in Clinical Trials” issued September 9, 2010 (75 FR 54889). Comments we received on the draft guidance have been considered and the guidance has been revised. The revision: (1) Replaces the term “suicidality” with the terms “suicidal ideation and behavior”; (2) provides an expanded set of the Columbia Classification Algorithm for Suicide Assessment (C-CASA) categories, along with definitions and explanations; (3) revises the advice on which trials and patients would need assessments of suicidal ideation and behavior and the timing of such assessments; (4) addresses concerns about the time burden of assessments; (5) addresses questions about the possible value of the assessments providing protection for patients in the trials themselves; (6) makes it clear that use of an assessment instrument that directly classifies relevant thoughts and behaviors into C-CASA categories

eliminates the need for any additional coding; (7) provides multiple additional references; and (8) revises advice on evaluation of alternative instruments.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on prospective assessment of occurrence of suicidal ideation and behavior in clinical trials. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

## II. Comments

Interested persons may submit to the Division of Dockets Management (see ADDRESSES) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

## III. Electronic Access

Persons with access to the Internet may obtain the document at either <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <http://www.regulations.gov>.

Dated: August 9, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012-19993 Filed 08/14/2012 at 8:45 am; Publication Date: 08/15/2012]